REMARKS

Summary of the Examiner's Actions

The examiner rejected 1, 4, 9 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Horbaschek *et al.*, U.S. Patent No. 4,937,848 ("the '848 patent") in view of Avinash, U.S. Patent No. 6,556,720 ("the '720 patent"). Applicant acknowledges the rejection under 35 U.S.C. § 103(a). The examiner objected to Claims 8 and 10 as being dependent upon a rejected base claim and indicated that each would be allowable if rewritten "to overcome the rejection(s) under 35 U.S.C. §112, second paragraph, set forth in this Office action" and to include all of the limitations of the base claim and any intervening claims. Applicant appreciates such indication. However, Applicant respectfully submits that no such rejections under 35 U.S.C. §112, second paragraph, were set forth. The examiner allowed Claims 3, 6, 11 and 12. Such indication is appreciated by the Applicant.

Examiner's Response to Applicant's Arguments

PET devices vs. X-ray devices

The examiner in the instant case has stated that "the X-ray tube and positron emission tomograph device both are image-acquiring devices used to obtain X-ray images. Positron emission tomograph produces electronic X-ray image data." While it is agreed that both the X-ray device and the PET device are image-acquiring devices, Applicant respectfully disagrees with the examiner in his understanding that a PET device is used to obtain X-ray images. Applicant would point out that it has long been established that the two modalities are quite distinct and are both useful for different purposes. In fact, due to the distinct benefits from the two modalities, there is much research currently being performed and progress is being made to integrate the two modalities such that the data collected in each *compliments* the other. See, for example, U.S. Letters Patent Nos. 6,490,476 and 6,631,284, both issued to D.W. Townsend and R. Nutt. Each of these patents, and several of the references cited therein distinguish these two and other modalities, and highlight the usefulness of each. Further, they teach how they can be combined to produce more of a whole body picture.

In a nutshell, though, a PET device is used with a radiotracer injected into a subject. PET has gained significant popularity in nuclear medicine because of the ability to non-invasively study physiological processes within the body. Applications employing the PET technology for its sensitivity and accuracy include those in the fields of oncology, cardiology and neurology. Using compounds such as ^{11}C-labeled glucose, ^{18}F-labeled glucose, ^{13}N-labeled ammonia and ^{15}O-labeled water, PET can be used to study such physiological phenomena such as blood flow, tissue viability, and in vivo brain neuron activity. Positrons emitted by these neutron deficient compounds interact with free electrons in the body area of interest, resulting in the annihilation of the positron. This annihilation yields the simultaneous emission of a pair of photons (gamma rays) approximately 180° (angular) apart. A compound having the desired physiological effect is administered to the patient, and the radiation resulting from annihilation is detected by the PET device. After acquiring these annihilation "event pairs" for a period of time, the isotope distribution in a cross section of the body can be reconstructed. Note that X-ray systems do not detect coincident events, as will be discussed below.

PET data acquisition occurs by detection of both photons emitted from the annihilation of the positron in a coincidence scheme. Due to the approximate 180° angle of departure from the annihilation site, the location of the two detectors registering the "event" define a chord passing through the location of the annihilation. By histogramming these lines of response (the chords), a "sinogram" is produced that may be used by a process of back-projection to produce a three dimensional image of the activity. Detection of these lines of activity is performed by a coincidence detection scheme. A valid event line is registered if both photons of an annihilation are detected within a coincidence window of time. Coincidence detection methods ensure (disregarding other second-order effects) that an event line is histogrammed only if both photons originate from the same positron annihilation.

X-ray devices, on the other hand, are not used with a radiopharmaceutical, and do not detect physiological phenomena such as blood flow, tissue viability, and in vivo brain neuron activity. X-ray devices detect dense portions of the body, such as bone.

As has also been discussed in the prior art, the characteristics of the detectors for PET and X-ray devices are vastly different.

Data input to computer

The examiner continued that "Horbaschek's system X-ray tube also produces digitized data because the data is inputted to computer, and computer can only process digital data. Therefore, the data collected by the X-ray tube in Horbaschek is the same as the data collected by the positron emission tomograph device." Again, Applicant respectfully disagrees. It is well known that computers are capable of receiving and processing both digital and analog data. Applicant fails to understand the leap in logic that because data is input to a computer, it must be digital. While it is admitted that analog data is often *converted* to digital data within a computer via a digital-to-analog converter, it is certainly not conceded that only digital data is input to a computer and that only digital data is processed by a computer.

The discussion above regarding the distinctions between PET and X-ray devices applies here as well. In view of these distinctions, and further in view of the understanding that computers are capable of receiving and processing both digital and analog data, Applicant does not agree that simply because Horbaschek discloses an X-ray device which collects data and inputs the data to a computer, that that data is digital data and is the same as data collected from a PET device. Based solely of the well-known fact that PET data is patently distinct from X-ray data prevents one skilled in the art from even broaching the question of whether the data is in digital or analog form.

New reference held in abeyance awaiting argument from Applicant

The examiner continued that "[i]f applicant insists the image-acquiring device needs to be PET, then the examiner prepares to cite a new reference in the following office action to show that the PET is an alternative to the X-ray system." Applicant would have appreciated such a citation without being provoked to request such. Examiner is directed to MPEP § 706 which states in part that "[t]he goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity. ... Although this part of the Manual explains the procedure in rejecting claims, the examiner should never overlook the importance of his role in allowing claims which properly define the invention."

In the instant case, the examiner is apparently aware of some patent that equates the two modalities of concern. However, he has withheld that from the Applicant and not afforded him the opportunity to respond to such. In the event that examiner deems a prior art reference not yet cited but held in abeyance for the purposes of refuting Applicant's argument that PET and X-ray devices are not the same, it is respectfully submitted that such a citation is *contra* to the MPEP and should at least not render final a subsequent Office Action in response to this paper.

Real time processing

Finally, the examiner indicated that "[w]ith regard to the limitation of 'real time', the examiner would like to direct the applicant's attention to figure 1, as the data 9 [sic] and 10 [sic] comes into computer, the data is immediately processed to be transformed from one coordinate system to another with no delay. Therefore, such transformation process is a real time process."

Applicant respectfully disagrees with the interpretation of the examiner on several counts. Specifically, reference numerals "9" and "10" do not refer to data, but refer to the patient support (col. 3, l. 28) and position transmitters (col. 3, l. 36), respectively. The data from these components is input to the computer 11 via lines 32 and 31, respectively. The data does not correspond to coincident events in PET, as set forth in the claims of the present application. There is no indication as to whether this data is processed in real time, or whether it is stored in memory for processing at a later time. To infer that the data is immediately processed to be transformed from one coordinate system to another with no delay is not supported in the Horbaschek specification. However, it is not the Applicant's contention that he has invented the concept of real time processing on a computer. Further, it is respectfully submitted that the data pointed out by the examiner as being processed by the computer in Horbaschek is not the same type or volume of data being collected and processed in the present application. As stated in Applicant's previous response, at the time of the '848 invention, and even still today, the performance of any calculation on data as it is collected, or in "real time," is difficult due to the volume of data collected and the hardware requirements for accomplishing such processing. It is more common for batch processing to be employed to accomplish this task. More specifically, the raw data is typically stored and processed at a time when the computer is not being used to collect data.

Rejections under 35 U.S.C. § 103(a)

A rejection under 35 U.S.C. § 103(a) must be supported by a prima facie case of obviousness. MPEP § 2142. "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." MPEP § 2142, pg. 2100-121.

The first element in establishing a prima facie case of obviousness is that "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings." MPEP § 2143. The second element is that there must be a reasonable expectation of success. *Id.* The third element is that "the prior art reference (or references when combined) must teach or suggest all the claim limitations." *Id.* "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a prima facie case of obvious was held improper); *see* MPEP § 2143.01.

The relevant facts for finding obviousness relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness such as long felt need, commercial success, the failure of others, or copying. *Graham v. John Deere Co.*, 148 U.S.P.Q. 459, 467 (U.S. 1966). The obviousness analysis articulated by the United States Supreme Court in *Graham* requires that "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Id.*

With respect to Claim 1, and subsequently with respect to Claims 4, 9 and 13, the Examiner continued his rejection from the previous Office Action, but conceded that Horbaschek does not explicitly disclose that the data is collected by a POT device. While the '848 patent teaches the use of digital pipeline latches and parallel multipliers to correct for the well-ordered 2-D and 3-D motion of the X-ray tube relative to the stationary or slow-moving patient couch, such motion is by nature regular and repetitive. This is proven from the use of the horizontal and vertical "sawtooth" voltage generators 18 and 19, respectively.

In contrast, the present invention is used to correct for random 3-D and 6-D motion of the patient relative to the stationary or predictably rotating PET detector array. The motion of the patient is unpredictable, as it is due to normal patient physiology such as coughing, sneezing, relaxing, and nervous disorders. It is also impossible to predict the precise 3-D angle of each gamma pair emitting from the patient.

In the '848 patent, the X-ray tube and X-ray beam are moved relative to the patient. The apparatus and method employed are to correct the single-beam projection data in mass. The single beam is only in one position at a time. While the beam is in this one position, the apparatus is collecting many hundreds of thousands of X-ray photons. The correction apparatus may only correct for the single X-ray beam in any particular orientation, while the sawtooth waveforms are at a particular phase.

In contrast, due to the nature of PET, the present invention is provided to correct from 100 million to 1 billion gamma pair lines-of-response (LORs) which are emitted from the patient at many random angles and orientations relative to the PET detector array. Because PET in its emission of the gamma pair LORs at many angles for each position is significantly different from X-ray tube techniques used for transmission of beams at a particular angle for each position, the demands of the present invention are profoundly more complex and demanding for rapid response.

The '848 device detects beams within a 2-D assembly including an X-ray image intensifier and a video camera. This assembly is placed on one side of the patient as illustrated. In the present invention, however, the gamma pair LORs are detected with a 3-D array of gamma detectors. This array is typically organized in a cylindrical configuration at least partially surrounding the patient.

The Examiner stated that "Avinash at column 4, lines 60-64, teaches using a positron emission tomograph device to acquire image data. At the time the invention was made, a person of ordinary skill in the art would have been motivated to use a positron emission tomograph device to obtain electronic X-ray image instead of an X-ray tube because Avinash at column 4, lines 60-64, clearly teaches positron emission tomograph is an alternative to the X-ray system."

With all due respect, Applicant again disagrees with this interpretation of Avinash. It is presumed that this reference, or a prior art reference with similar language, is what the examiner was referring to when he said he was prepared to cite a new reference to show that PET is an alternative to X-ray. However, that is not at all what Avinash has taught.

Avinash teaches a method for enhancing and correcting digital images. As a point of interest, at Col. 4, lines 30-32, Avinash teaches that "[s]ignals sensed by coils **20** are encoded to provide digital values representative of the excitation signals emitted at specific locations within the subject...." This clearly supports Applicant's position that data acquired from an X-ray device is not digital, and that data input into a computer is not necessarily digital. Then at Col. 4, lines 42-45, Avinash teaches that the "digital values representative of each pixel in the acquired image ... are then stored in memory circuit **26** for subsequent processing and display." This supports Applicant's position that it is not an appropriate logical step to say that because data is input into a computer that it is processed immediately.

On a more substantive look at Avinash, however, it is respectfully submitted that what Avinash does teach is a method for processing data, and that that method may be used to process image data acquired from various sources, including among others, X-ray systems and PET systems. This does not yield a logical conclusion, however, that X-ray systems may be substituted for PET systems to acquire PET data, and vice versa. It only means that the data collected from each may be processed similarly using the method of the Avinash patent. Before the argument is made, thought, Avinash further does not teach that the data is the same. Further, it is questioned as to whether there is sufficient disclosure in Avinash to make such a statement in that there is no teaching as to how the Avinash method is adapted for

each use, since the data acquired from each modality is different from every other modality.

Further, a person of ordinary skill in the art would *NOT* have been motivated to use a positron emission tomograph device to obtain electronic X-ray image instead of an X-ray tube because a positron emission tomograph device *CANNOT* be used to obtain an electronic X-ray image. Applicant would appreciate citation of any reference that teaches how such could be accomplished.

From the distinctions between X-ray v. PET as have been explained, it is respectfully submitted that those skilled in the art recognize that the prior art of record does not obviate the claims of the present invention. Specifically, the prior art of record does not teach a device for on-line correction of patient motion. Further, the prior art of record does not teach such a system for use in 3-D PET. Nor does the prior art of record teach such a device wherein a PET tomograph device is used to collect coincidence event and position data. Because of these and other distinctions, it is respectfully requested that the Examiner's rejection of Claims 1, 4, 9 and 13 be reconsidered and withdrawn.

Claim Objections

Claims 8 and 10 have been rewritten in independent form, including all of the limitations of the base claim and any intervening claims. Specifically, new Claim 14 includes all of the limitations of Claims 8 and 13, with Claim 8 being cancelled without prejudice. New Claim 15 includes all of the limitations of Claims 9, 10 and 13, with Claim 10 being cancelled without prejudice. Applicant respectfully submits that claims 14 and 15 are in condition for allowance.

Summary

In view of the presentation of new Claims 14 and 15, the cancellation of Claims 8 and 10, without prejudice, and the arguments presented herein, it is believed that the above-identified patent application is in a condition for the issuance of a Notice of Allowance. Such action by the examiner is respectfully requested. If, however, the examiner is of the opinion that any of the drawings or other portions of the application

are still not allowable, it will be appreciated if the examiner will telephone the undersigned to expedite the prosecution of the application.

Please charge any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 16-1910.

Respectfully submitted,

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